TRIP REPORT

Japan Request to be Recognized Free of Foot and Mouth Disease Robert T. Tanaka, Area Director APHIS, USDA, Seoul, Korea January 16-19, 2001

Schedule

January 16: a.m. - Briefin

a.m. - Briefing for US Embassy, Tokyo

p.m. - Meeting with Ministry of Agriculture, Forestry and Fisheries (MAFF), Tokyo, to obtain more detailed information concerning the report that was

submitted to APHIS

January 17:

a.m. - Travel to Miyazaki

p.m. - Meeting with officials of the Agriculture and Fisheries Department of the

Miyazaki Prefectural Government

January 18:

a.m. - Site visit to outbreak farms and Miyazaki Livestock Hygiene Service Center

p.m. - Travel to Tokyo

January 19:

a.m. - Debriefing with MAFF

p.m. - Debriefing with US Embassy

Contacts

US Embassy, Tokyo:

James Mackley, Regional Director, APHIS, USDA Hiroko Kani, Agricultural Assistant, APHIS, USDA Suzanne Hale, Minister-Counselor, FAS, USDA Casey Bean, Agricultural Attaché, FAS, USDA

Animal Health Division, Livestock Industry Bureau, Ministry of Agriculture, Forestry and Fisheries, Tokyo:

Kenichi Matsubara, Director Shiro Yoshimura, Chief, Office of International Animal Heath Affairs Kazuo Ito, Deputy Director Yoshio Morinaga, Deputy Director H. Ogura, Deputy Director, Domestic Quarantine Kazuhisa Hoshino, Veterinarian Department of Exotic Disease, National Institute of Animal Health, Tokyo:

Koichi Namba, Director

Agriculture and Fisheries Department, Miyazaki Prefectural Government, Miyazaki:

Kenzo Hatsushika, Director, Livestock Production Department Yukito Shimazaki, Deputy Director-General Yuichi Osawa, Deputy Director-General Rihachi Kuroki, Chief in Charge of Animal Health Tamotu Taniguchi, Animal Protection, Livestock Production Division Kazuki Sakamoto, Animal Health, Livestock Production Division

Miyazaki Livestock Hygiene Service Center, Miyazaki:

Hirode Nagata, Director Midori Saita, Director, Inspection Division Junzo Mizobe, Veterinarian Kazuhiko Toyama, Animal Health

Activities/Accomplishments

Obtained follow up information on Japan's request to be recognized free of foot and mouth disease by USDA. (APHIS questions and AHD responses are attached.)

Conducted site visits to premises affected by the outbreak.

Communicated the procedures for changing the US federal regulation regarding reinstating Japan as a country recognized free of foot and mouth disease, including a possible 18-24 month timeline.

Obtained questions regarding FSIS approval for reestablishing export of Japanese beef to the US. These will be forwarded to FSIS-Washington, DC.

Recommendations

Recommend Japan be recognized as free of foot and mouth disease, pending review of this report, especially the questions and answers. This recommendation is based on the written report submitted to APHIS, my meeting with federal and local government officials, and my site visits to outbreak areas.

Recommend APHIS experts review how MAFF determined herd status of surveillance farms based on serologic titer. (MAFF explanation is included in APHIS questions and AHD responses.)

Request that FSIS procedures for reinstating Japan's export trade be forwarded to the Ministry through the APHIS-Tokyo office.

Acknowledgments

Thanks to Dr. Mackley and the entire APHIS-Tokyo staff for their kind help arranging my trip. In addition, thanks to Dr. Ito for coordinating our MAFF meeting, to Dr. Hoshino for traveling to Miyazaki, and to Drs. Taniguchi and Kuroki for coordinating our visit to Miyazaki. A special thanks to Ms. Hiroko Kani for providing language interpretation and technical assistance throughout my visit.

APHIS Questions and MAFF Responses From January 16, 2001 Meeting

Serologic Surveillance

Question - Different sampling protocols were used in Miyazaki and Hokkaido Prefectures. For example, in Miyazaki Prefecture, 3 animals were used in herds of 30-100 animals, whereas in Hokkaido, the sampling was increased to 25 animals in herds of 40-100 animals. Why was sampling conducted at a lower level in Miyazaki?

Response - In Miyazaki the symptoms were not clear. Therefore, there was a fear that the disease may have spread without detection. So the strategy was to conduct widespread sampling in a very short time period. This necessitated smaller sample sizes in Miyazaki compared with Hokkaido. Since the farm size is small in Miyazaki, most animals were checked using this sampling scheme.

Per Annex 4, intensive sampling was conducted within a 1 kilometer radius and for farms epidemiologically linked. Section 2.1.2 indicates that ten animals from each farm be sampled. Because most farms were very small, this effectively constituted a large percentage of the animals present.

Comment - None.

Question - ELISA test for antibodies: Does Japan use the liquid-phase blocking ELISA prescribed by OIE? If so, why doesn't Japan consider any titer in excess of 1/40 as a positive? If not, please provide the test methodology.

Response - Liquid-phase blocking ELISA is used and was provided by Pirbright Laboratory. Nonspecific reactions made test interpretation difficult. Japan experienced approximately 5% nonspecific reactions, compared to others who reported up to 20%. The test kit that was used indicated that 1:40 be considered positive. Testing 1,086 known negative serum samples from the US and Australia, 56 were positive at 1:40. Dr. Kitching from Pirbright Laboratory was consulted on where to make a cutoff. It was decided that 1:181 would be considered positive. This was based on comparison with serum neutralization test results. The attached table shows results for the outbreak samples in this range. Therefore, Japan is confident that 181 is a reasonable cutoff point. Studies, for example in the US, have shown that there can be nonspecific reactions for titers as high as 362. The actions taken as a result of screening tests are shown on page 33. (Note -- the cutoff points at each level are indicated in handwriting.)

Comment - I defer to APHIS experts for their assessment of this explanation.

Epidemiology

Question - Farm D was not epidemiologically linked to Farms A, B, and C. Is imported forage considered to be the most likely source of the outbreak on Farm D?

Response - The most likely source was either rice straw from Taiwan or sugar cane from Indonesia. There was no clear source implicated.

Comment - None.

Question - Farm D is a feedlot. Prior to the outbreak, when was the last time that animals were sent to slaughter from this feedlot?

Response - The last time was April 29. There were 705 cattle in the feedlot at the time of the outbreak. Serologic sampling revealed that most of the positive animals were younger. Sampling of the source farms were all negative. It is suspected that the virus was introduced into the feedlot in late March or early April.

Comment - Some serum samples taken April 7 and April 24 were positive. On April 29 the herd was subjected to the "Herd Under Quarantine Program" as described in Annex 5. Probang sample taken May 9 were positive. On May 11, all the animals were suspected to be infected. The herd was stamped out by May 15. This relates to the previous question concerning titer interpretation and whether the Annex 5 provisions are considered acceptable. Again, I defer to APHIS experts for their assessment.

Preventive Measures/Imports

Question - On page 17 of the Final Report, it states that "import inspection was strengthened for straw and forages imported from FMD infected countries." Please explain.

Response - On March 27, regulations were imposed which required rice straw from Taiwan be treated with formalin. On March 30, the requirement was expanded to include rice straw and hay from all FMD infected countries. The formalin requirement effectively stopped imports for feed purposes since the forage is not palatable after treatment.

An existing requirement was for straw and hay from China to be heat treated at 80 degrees C for ten minutes; the same plant protection requirement was for 86 degrees C for four minutes. This shorter treatment schedule was shown to be effective against FMD as well. In early December 2000 the requirement was changed so that straw and forage from FMD countries be heat treated at 80 degrees C for ten minutes.

Comments - None

Question - Also, it states that "farmers were instructed not to use straw and forage, for feeding and bedding, which has been imported." Does this mean that farmers are prohibited by law from using imported straws and forages? How is this monitored and enforced?

Response - Farmers are given advice and instructions from government officials. These do not have the force of law or regulation. In practice, farmers were subject to close scrutiny because of the serologic surveillance. Because of the culture, people will follow "instructional guidelines."

Comment - My site visits and experience with the Japanese culture makes me believe that farmers would follow instructional guidelines.

Question - On page 16 it states that imported straws and forages are subject to inspection and fumigation (disinfection?). How is this accomplished, i.e., what chemical is used to fumigate/disinfect?

Response - For those shipments arriving in Japan, formalin is used. There are specifications for vacuum chambers and the concentration of formalin gas. This method has not been used since March 31. For treating in the country of origin, heat is used.

Comment - None.

Question - In Annex 8, Uruguay is listed among the countries from which Japan imports animals and animal products. What action did Japan take in response to the recent outbreak of FMD in Uruguay?

Response - On October 25, 2000, Japan suspended the importation of beef from Uruguay based on a notification of a suspected outbreak. The suspension included meat slaughtered on or after October 2. On November 7, the enforcement law was changed to prohibit all cloven-hoofed animals and animal products from Uruguay. This law is still in effect.

Comment - None.

Veterinary Force

Question - On page 6 it states that some private veterinarians are appointed as veterinary inspectors. How are these veterinarians selected? What functions do they perform? Are they held accountable to certain standards? If so, how is this accomplished?

Response - Not all Prefectures used private veterinarians during the outbreak. If needed, veterinarians were selected from those in livestock practice. They perform the same functions as the prefecture veterinarians. During the outbreak, they interviewed farmers and collected blood samples. Veterinarians receive instructions from the Prefectural government who carry out the policies of the National government.

Comment - I learned that there are few if any federal animal health officials working outside of Tokyo headquarters. National programs are implemented by the Prefectures with direction from the Ministry. If private assistance is needed at the local level, the Prefectures will coordinate the arrangements. This is true even in a national emergency, such as the FMD outbreak control and eradication. However, during the outbreak, there were always two or three Ministry officials present in Miyazaki. They coordinated national policies for laboratory and other procedures for control and eradication.

Question - When movement controls are established around a farm, how are these controls enforced? For example, do veterinary inspectors receive assistance from police or other authorities?

Response - Movement controls were placed on vehicles, particularly those associated with agriculture. Police helped by stopping all traffic at "sterilization points" where vehicles were disinfected. Prefectural government, agriculture officials, including meat inspectors, helped during the outbreak.

Comment - I visited one sterilization point. Sodium carbonate was used to disinfect vehicles. Remnants of the chemical were still present. There were 21 sterilization points for Miyazaki. Almost all were two lane roads which were easy to control. One highway sterilization point was close after only one day. This was because of the difficulty controlling vehicles, safety concerns, and the relatively few high risk vehicles.

Additional Questions from Reviewer

Animal Identification

Question - On page 9 the report states that there is no compulsory animal identification system for animal health. How does this affect trace back ability?

Response - There is generally a good system by local farm association, breed registry, or individual farm.

Comment - During my site visit I was able to see the registry information for some Wagyu heifers. It included parentage information, description, and a nose print. Animals had ear bangle tags as well.

Question - On page 17 a number of planned measures are mentioned. What is the status of these?

Response - Epidemiological surveillance has been enhanced by an automated laboratory results system. Import restrictions effectively reduced the risk of importing the disease. Infectivity studies are in progress, including gene sequencing and inoculation studies. Some of these have already been done, for example at Plum Island lab. The national emergency response manual is being reviewed in light of the outbreak. Some proposed changes include the following. One change would lengthen the time allowed for stamping out a farm from 48 hours to 72 hours. This is more reasonable since herd size is increasing. Another change would shift the responsibility of killing animals from the government to the farmer. Finally, one change would increase the isolation period for suspect animals from ten days to twenty days.

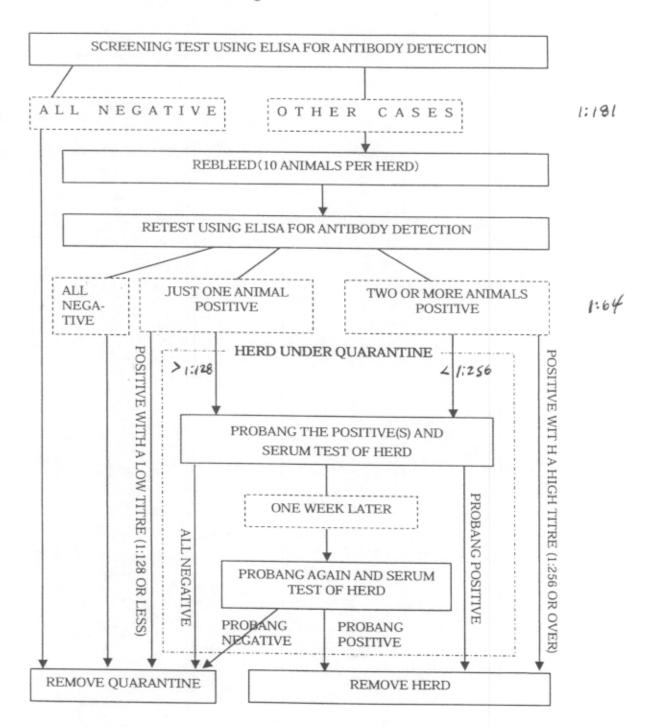
Comment - None.

Question - After explaining the US federal regulation process and the possible time line, what is the potential trade impact?

Response - There is a small but symbolic export of Wagyu beef to the US. Prior to the outbreak, the average volume of trade was about 35 metric tons. Although this is a relatively small amount, it is important since Wagyu is such a national symbol of excellence in the livestock industry.

Comment - There is an obvious national pride in Wagyu meat. Expediting the regulatory process would be very much appreciated by the Ministry. I made a point to clearly inform Ministry, Prefecture, and other contacts on the federal regulation process. In addition, FSIS procedures for reinstating trade should be forwarded to APHIS-Tokyo for delivery to the Ministry.

Outline of Tests under the Program



Relation between ELISA-Titer and NT-Titer

ELISA-Titer	NT-Titer	ELISA-Titer	NT-Titer	ELISA-Titer	NT-Titer
2896	1024	181	<4	181	<4
2896	1024	181	8	181	4
1488	512	181	<4	181	4
>362	512	181	4	181	4
>362	1024	181	<4	181	<4
>362	512	181	<4	181	<4
>362	512	181	<4	181	<4
>362	512	181	8	181	8
>362	128	181	< 4	181	<4
>362	8	181	4	128	<4
>362	4	181	<4	128	4
>362	8	181	16	128	<4
>362	64	181	<4	128	< 4
>362	32	181	< 4	128	< 4
>362	16	181	<4	128	8
>362	< 4	181	16	128	4
>362	128	181	<4	128	<4
362	<4	181	4	128	<4
362	8	181	<4	128	<4
>256	1024	181	<4	128	< 4
>256	1024	181	<4	128	4
>256	512	181	<4	90	<4
>256	512	181	< 4	90	<4
>256	256	181	<4	90	8
>256	1024	181	<4	90	4
>256	512	181	<4	90	<4
>256	1024	181	<4	90	<4
>256	1024	181	4	90	<4
>256	1024	181	<4	90	4
>256	4	181	8	90	<4
>256	4	181	4	90	<4
>256	<4	181	<4	64	8
>256	4	181	< 4	64	<4
>256	<4	181	<4	64	<4
>256	256	181	<4	45	<4
256	<4	181	4	45	8
256	8	181	4	45	<4
256	8	181	<4	45	<4
256	<4	181	<4	45	<4
256	8	181	<4	45	<4

According to "Manual of Standard for Diagnostic Test and Vaccine" a titer of 1/11 or less is considered to be negative.

This Table shows that ELISA titer less than 181 are all negative by NT.